JUL - 5 2000

ADMINISTRATIVE INFORMATION K001337

Manufacturer Name:	The Daniels Corporation
Official Contact:	Randy Shillington Vice-President of International Business The Daniels Corporation 1772 Los Arboles #J112 Thousand Oaks, CA 91362 Telephone (805) 552-0733 Fax (805) 552-0734
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone (858) 792-1235 Fax (858) 792-1236

DEVICE NAME

Classification Name:	Accessory to hypodermic single lumen needle
Trade/Proprietary Name:	Daniels Sharpsmart™ reusable sharps container
Common Name:	Reusable sharps disposal container

ESTABLISHMENT REGISTRATION NUMBER

The Daniels Corporation has not yet obtained an Establishment Registration Number.

DEVICE CLASSIFICATION

The Daniels Sharpsmart container is an accessory to sharps, which are Class II devices according to 21 CFR § 880.5570. Therefore, the Sharpsmart container is a Class II device. Product codes 80FMI and 80MMK have been applied to reusable sharps containers.

PERFORMANCE STANDARDS

No performance standards have been established under Section 514. The Daniels Sharpsmart container complies with Occupational Safety and Health Administration (OSHA) standards on bloodborne pathogens as outlined in 29 CFR § 1910.1030 and Department of Transportation (DOT) regulations controlling the transport of regulated medical waste as outlined in 49 CFR § 173.197. The Daniels Sharpsmart container also complies with the Australia/New Zealand Standard for Reusable containers for the collection of sharp items used in human and animal medical applications (AS/NZS 4261:1994).

LABELING

Draft product labeling includes a statement that the container is not intended to be reprocessed by any party not authorized by The Daniels Corporation.

GENERAL DESCRIPTION

The Sharpsmart container is intended to be used in patient rooms, medication rooms, operating rooms, physicians' offices or any other patient care area requiring the use of a sharps container. It is a two-piece injection-molded container made from a polypropylene copolymer. There is a handle on the lid to facilitate easy handling. Once the Sharpsmart container is mounted, the lid is opened, moving the tray into its receiving position. When a sharp is ready for disposal, it is placed on the gravity-activated tray, which then closes and deposits the sharp in the container, after which the tray returns to its receiving position. The tray is designed to deposit the sharps in a horizontal orientation, which allows for best use of the interior space. The lid can be closed temporarily for transportation. When the container is ready for reprocessing, the lid is closed and locked by means of latches on either side. After these latches are closed, a special tool is required to open the container.

Sizes

The Daniels Sharpsmart container is provided in three sizes. The largest unit (S 32) has a total air volume of 33.8 quarts, fill capacity of 25.0 quarts and an empty weight of 5.1 lb, with outer dimensions of 24"h x 13.5"w x 6.6"d. The medium unit (S 22) has a total air volume of 21.6 quarts, fill capacity of 15.5 quarts and an empty weight of 4.4 lb, with outer dimensions of 17.3"h x 13.5"w x 6.6"d. The small unit (S 14) has a total air volume of 14.8 quarts, fill capacity of 7.0 quarts and an empty weight of 2.9 lb, with outer dimensions of 11.0"h x 13.5"w x 6.6"d.

Materials

The bin and lid of the container are made of impact modified polypropylene co-polymer. The liner, upper and lower trays, right and left lid supports, handle and catches are all made from polyphenyleneoxide (Noryl). The window is made from a random copolymer polypropylene, and the seal is made from a rubber modified polyethylene. All components are injection molded except the wire spring and the gasket which is extruded.

DESIGN FEATURES/SPECIFICATIONS/VALIDATION

The Sharpsmart container is designed to provide a safe method of sharps disposal that also lessens the environmental impact of the sharps waste. Unused Sharpsmart containers have been tested according to the ECRI recommendations (Evaluation: Sharps Disposal Containers, *Health Devices*, vol 22, nos. 8-9, August-September 1993), and AS/NZS 4261:1994. The containers were also tested according to the AS/NZS standard after being filled, opened, emptied and sanitized 500 times. In addition, the containers were tested according to requirements of the Australian Code for the Transport of Dangerous Goods (ADG Code).

Sharps access and closure

The gravity-activated tray on the container allows for the depositing of sharps while preventing the removal of sharps. The tray moves into the receiving position when the container is opened. When a sharp is deposited on the tray, gravity causes the tray to close and the sharp to be deposited into the container. The inlet is designed so that the tray prohibits fingers and hands from entering the contents compartment by completely covering the opening of the contents compartment, even as it is closing.

The container can be closed temporarily with the latch located on the front of the lid, as might be needed for transportation from one area of use to another. The container can also be locked shut with the two latches on the sides of the container, when the container is full and/or ready for transportation to the reprocessing plant. Once it is locked shut, the container cannot be opened without the use of a special tool.

The container has a rubber modified polyethylene seal which is designed to hold liquid contents inside the container in the event that the container falls over or is dropped when it is closed. When the Sharpsmart containers were tested for impact resistance, integrity of the closure device and leakage according to Appendix B of AS/NZS 4261:1994, no leakage was observed.

Overfill Detection

Each Sharpsmart container has a view window on the front of the container. The view window has a fill line approximately 2/3 of the way up the window to allow the user to know when the container is nearing its capacity. Once the container is full, the flap closes and cannot be opened. This prevents the container from being over-filled.

Mounting Accessories/Locking Mechanism

The Sharpsmart container is mounted to help keep the container stable and to enable positioning in point of use areas. Mounting is accomplished though the use of a special bracket or cradle. The Sharpsmart container can be mounted on a wall, cart, bench, bench-top, IV pole or inside a cupboard. A mobile stand, with or without a handle, is also available.

A locking mechanism is available to secure the container to the wall. Once the mechanism is in the locked position, the container can not be removed from the wall without the key.

Additional design features

In addition to the design features mentioned above, the Sharpsmart container complies with the following OSHA regulations:

- has no feature to bend, break or shear needles
- does not have a needle unwinder
- is not a container for reusable sharps

SECONDARY CONTAINERS

The Sharpsmart container has received Department of Transportation approval, and does not require a secondary container for transportation to the downstream decanting plant. The primary container is closable, contains all contents and prevents leakage during handling, storage, transport and shipping. The drop tests and stacking tests have been discussed above.

DOWNSTREAM DECANTING PROCEDURES

All reprocessing of Sharpsmart reusable sharps containers will be performed in facilities established as joint ventures between The Daniels Corporation and qualified medical waste treatment providers. Daniels will supply all the decanting and washing equipment and will ensure that the facility meets all regulatory requirements, including compliance with FDA Quality System Regulations (21 CFR 820).

EQUIVALENCE TO MARKETED PRODUCT

Daniels submits the following information to demonstrate that the Sharpsmart Reusable Sharps Container shares indications, design principles, materials and properties with the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices: Sterisharp 2.5-Gallon RSDC (K991612) from Sterilogic Waste Systems, Inc., Sharps Away (K943765) from Biomedical Waste Systems, Inc. and B-D Guardian Patient Room (single-use) sharps containers (K943575, K943141).

Intended Use

The indications for use of the Daniels Sharpsmart Reusable Sharps Container are not new indications in that they are the same as or are included in those for the predicate devices. Sharpsmart and the predicate devices are containers intended to be used for the disposal of contaminated medical sharps in health care facilities.

Design and Materials

The design and functional characteristics of the Daniels Sharpsmart and the predicate devices are similar. They are constructed from polymeric materials. The Sterisharp and Sharps Away containers are intended to be emptied, cleaned and reused. All of the devices conform to national or international standards for puncture resistance, impact resistance and leakage. They have means to prevent contact between the user and the contents, and are designed with features to easily and safely determine if they are full. They do not have features to bend, break or shear needles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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The Daniels Corporation
C/O Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K001337
Trade Name: Daniels Sharpsmart Reusable Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: April 25, 2000
Received: April 27, 2000

Dear Mr. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Daniels Sharpsmart Reusable Sharps Container

Indications for Use:

Reusable containers intended to be used for the disposal of contaminated medical sharps in health care facilities

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use X

Alan S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001337